

**Amendments to the Drawings**

Applicants enclose herewith one sheet of replacement formal drawings, including FIGS. 1, 1A, and 4. FIG. 4 has been labeled on the replacement sheet.

Attachment: One Replacement Drawing Sheet  
One Annotated Sheet Showing Changes

### **REMARKS/ARGUMENTS**

Applicants have carefully reviewed the Office Action mailed on July 6, 2007. Applicants respectfully traverse (and do not concede) all objections, rejections, adverse statements, and adverse assertions made by the Examiner. A replacement sheet of formal drawings is appended herewith. Claims 22-24, 28-52, 60-77, 79, and 80 have been canceled without prejudice and claims 1, 7, 25, 53, 78, 81, 85, and 86 have been amended. support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added.

### **Inventorship and Corrected Filing Receipt**

A request to correct inventorship under 37 C.F.R. §1.48(c) was filed on December 17, 2004. With that filing, Applicants additionally requested the issuance of a corrected filing receipt reflecting the change of inventorship. Applicants have not yet received an indication that the inventorship has been corrected, and have not yet received a corrected filing receipt reflecting the change of inventorship. Applicants respectfully request that these be issued in due course.

### **Drawings**

The drawings were objected to. The Examiner indicated that Figure 4 in the drawings submitted on January 16, 2006 has not been labeled in the drawings. In the last reply to the Office, Applicants indicated that on February 13, 2004, Applicants filed an electronic submission for Pre-Grant Publication with formal drawings. The Examiner indicated that there was no record of a submission in the file. It appears that the February 13, 2004 submission did not reach the Examiner. To address this issue, Applicants have attached herewith one sheet of replacement formal drawings, in which FIG. 4 has been labeled. Applicants respectfully submit that these drawings are in compliance with 37 C.F.R. §1.121(d) and overcome the objection.

### **Claim Rejections under 35 U.S.C §103**

Claims 1-4, 6-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59, 76-81, and 85-87 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jacobsen et al. in U.S. Patent No. 6,579,246 in view of Shiber in U.S. Patent No. 5,135,531. Independent claims 1, and 7, as amended, recite a device including a coil that is formed by edge winding a wire that, prior to winding, has two substantially flat opposite non-parallel sides that are out of parallel by an angle, wherein the process of edge winding the wire into the coil causes the sides to become substantially parallel. These elements were previously presented in claims 76, 77, 79, and 80.

Neither Jacobsen et al. nor Shiber appear to teach such a structure. The Examiner asserts that one of ordinary skill in the art would recognized Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section. Applicants respectfully disagree. Shiber does not appear to teach how the helical casing 93 is formed and does not teach the specific structure recited in the claims. In particular, Shiber does not teach forming a coil from a flat stock, as asserted by the Examiner. The Examiner's assertions regarding the geometries achieved when forming a coil from a flat stock are thus not inherent in Shiber.

If the Examiner is considering the specific structure recited in the claims to be inherent in Shiber, Applicants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

(Emphasis added). Applicants submit that the claimed structure is not necessarily present in Shiber. It appears the Examiner is asserting that the Shiber device could be modified to achieve the claimed structure, which is not a proper basis for rejection.

The Examiner appears to have taken Official Notice with respect to claims 76-87, asserting that the concept and advantages of forming a coil from a wire having a substantially non-circular cross section having two substantially flat opposite non-parallel sides that are out of parallel by an angle prior to forming the helical coil are well known and expected in the art. Applicants submit that the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. Per MPEP 2144.04(C), Applicants respectfully traverse the taking of Official Notice and request the Examiner provide documentary evidence supporting the rejection in the next office action if the rejection is maintained.

Regarding independent claims 25 and 53, and the claims dependent thereon, the Examiner acknowledges that Jacobsen et al. fail to teach a coil being formed from a wire having a substantially non-circular cross section and that the cross-section has a greater dimension in the radial direction than in the axial direction. The Examiner asserts that it would have been obvious for one of ordinary skill in the art to modify the guidewire coil of Jacobsen et al. to include the use of a non-circular cross-section as taught by Shiber since it would provide another means of providing a flexible distal end for a guidewire. Applicants respectfully disagree.

Applicants submit that there is no suggestion or motivation for one of ordinary skill in the art to modify the coil structure of Jacobsen et al. with the coil of Shiber. The Examiner asserts that one of ordinary skill in the art would have been able to substitute the coil shape of Shiber with that of the coil shape of Jacobsen et al. without destroying the function of the guidewire. Applicants submit that this is not the correct standard for obviousness. In *KSR Int'l Co. v. Teleflex Inc.* (550 U.S. \_\_ 2007), the Supreme Court states:

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court's view, because “ ‘ “[o]bvious to try” has long been held not to constitute obviousness.’ ” *Id.*, at 289 (quoting *In re Deuel*, 51 F. 3d 1552, 1559 (CA Fed. 1995)).

Emphasis added, see page 10 of April 30, 2007 decision. The Court further states:

if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida and Anderson's-Black Rock* are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

See page 13 of the April 30, 2007 decision. Shiber teaches:

A void defined between the helical wire's coils serves as a barrier, holding the obstruction material during the atherectomy and restraining the cored material from freely rotating around the flexible guidewire, and to the extent that the obstruction material is rotated by the flexible catheter this rotation is translated by the helical wire to urge the cored obstruction material proximally in the continuous passage. The helical wire can be inserted into a tight obstruction by rotating it, threading it into the obstruction. In the process of threading, the helical wire pulls itself across the obstruction and anchors itself in the obstruction material.

See column 4, line 60 through column 5, line 4 Shiber thus appears to teach the helical coil improving the atherectomy device by providing a means for coring through an obstruction and providing a barrier for the cored material, to prevent the cored material from freely rotating around the guidewire. Applicants submit that one of ordinary skill in the art would have no reasonable expectation and would not recognize that the coring helical coil of Shiber would improve the guidewire of Jacobsen et al. in the same way. Shiber and Jacobsen et al. are directed to different devices with different structures and functions.

The Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. Applicants submit that just because one could combine structures described in Jacobsen et al. and Shiber without destroying the function of Jacobsen et al. is not a proper ground for an obviousness rejection.

Claim 25 recites that the core wire comprises an abrupt change in cross-sectional dimension between the proximal section and the distal section, that the core wire is attached to the tubular member at least at the proximal end (of the tubular member), and that the proximal end (of the tubular member) abuts the abrupt change in cross-sectional dimension. Jacobsen et al. does not appear to teach or suggest this limitation. Indeed, a medial coil 532 is disposed between the micromachined tubing 514 and the core wire 501 in Jacobsen et al. Because of this, the micromachined tubing 514 does not appear to abut any portion of the core wire 501. Jacobsen et al. does not appear to teach or suggest all the claim limitations of claim 25. Shiber fails to overcome this deficiency.

For at least the reasons set forth above, Applicants respectfully submit that independent claims 1, 7, 25, and 53, and the claims dependent thereon are patentable over the combination of Jacobsen et al. and Shiber, to the extent that such a combination is even possible. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. and Shiber as applied to claim 7 above, and further in view of Lui in U.S. Patent Application Publication No. 2002/0010475. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. and Shiber as applied to claim 7 above, and further in view of Levine et al. in U.S. Patent Application Publication No. 2003/0009157. As discussed above, Jacobsen et al. and Shiber do not appear to teach or suggest that basic elements of independent claim 7, from which claims 13 and 18 depend. Lui et al. do not appear to teach or suggest what Jacobsen et al. and Shiber lack, thus even if one were to combine Jacobsen et al., Shiber, and Lui et al., one would not arrive at the claimed device. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. and Shiber as applied to claim 1 above, and further in view of Tsuji et al. in U.S. Patent No. 5,181,668. The elements of claim 76 have been added to claim 1. Jacobsen et al. and Shiber fail to teach the basic elements of claim 1 for the reasons set forth above. Tsuji et al.

fail to teach what Jacobsen et al. and Shiber lack. Further, there is no motivation or suggestion for one of ordinary skill in the art to combine the teachings of Tsuji et al. with Jacobsen et al. and/or Shiber. Tsuji et al. is directed to methods of inserting a wire into a pipe, such as a gas pipe, and injecting a liquid lining material into the pipe. See column 4, lines 20-35. Applicants submit that one of ordinary skill in the art of medical devices would have no motivation or expectation of success in looking to the pipe lining art, such as that taught by Tsuji et al., for modifying the coronary guidewire system of Jacobsen et al. Tsuji et al. is clearly non-analogous art to Jacobsen et al. and Shiber. Such a combination can only be motivated by the instant specification, which is clearly improper. Reconsideration and withdrawal of the rejection are respectfully requested.

### **Conclusion**

Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

CLARK C. DAVIS et al.

By their attorney,

Date: October 8, 2007

  
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